Declaration of Conformity

Manufacturer:
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Basic UDI-DI: Refer to Appendix
Product Name, Reference number, Intended Purpose: Refer to Appendix
Classification: Refer to Appendix

Conformity assessment procedure: Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics).

We herewith declare that the above-mentioned product(s) meet the Regulation (EU) 2017/746 of THE EUROPEAN PARLIAMENT AND OF THE COUNCIL and the transposition into national law.
All supporting documentation is retained at the premises of the manufacturer.
We, the manufacturer, are exclusively responsible for the DoC.

General Applicable Regulation:
REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017.

Applicable Standards:

EN ISO 23640:2015	EN ISO 14971:2019	EN ISO 18113-1:2024
EN 13612:2002	EN ISO 15223-1:2021	EN ISO 18113-2:2024
EN 13641:2002	EN ISO 13485: 2016	EN ISO 17511:2020
ISO TR 20416:2020	ISO 780:2015	ISO 20916:2019

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MOLDOVA EUROPEANĂ

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Name : Xiang Lei
Position: Director
Place: Shenzhen
Date of Issue: April 10, 2025

Appendix I

No.	Product Name	Specification	REF No.	Basic UDI-DI	Intended Purpose	Classification
1	Thyroid Stimulating Hormone (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	690060, 690061, 690062, 690063	6970341680320 5001HV	Thyroid stimulating hormone (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of thyroid stimulating hormone (TSH, thyrotropin) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of thyroid disorders.	Annex VIII, Class B, Rule 6
2	25-OH Vitamin D Total (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	693021, 693024, 693011, 693025	6970341680320 5002HX	25-OH Vitamin D Total (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of 25-OH Vitamin D in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of diseases related to vitamin D deficiency.	Annex VIII, Class B, Rule 6
3	Interleukin-6 (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	689023, 689024, 689017, 689018	6970341680320 5003HZ	Interleukin-6 (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of Interleukin-6 (IL-6) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of inflammation disorders.	Annex VIII, Class B, Rule 6
4	Procalcitonin (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	689021, 689022, 689013, 689014	6970341680320 5004J3	Procalcitonin (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of Procalcitonin (PCT) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of bacterial infectious diseases.	Annex VIII, Class B, Rule 6
5	Thyroid Peroxidase Antibody (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	690039, 690041, 690040, 690042	6970341680320 5005J5	Thyroid Peroxidase Antibody (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of thyroid peroxidase antibody (Anti-TPO) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of autoimmune thyroid diseases.	Annex VIII, Class B, Rule 6
6	Total Beta Human Chorionic Gonadotropin (Total β-HCG) eCLIA	50T, 2×50T, 100T, 2×100T	697039, 697040, 697041, 697042	69703416803 205006J7	Total Beta Human Chorionic Gonadotropin (Total β-HCG) eCLIA is an immunoassay reagent for in vitro quantitative determination of total beta human chorionic gonadotropin (Total β-HCG) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of pregnancy.	Annex VIII, Class B, Rule 6
7	Myoglobin (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	691033, 691034, 691015, 691016	6970341680320 5007J9	Myoglobin (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of myoglobin (MYO) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of acute myocardial infarction.	Annex VIII, Class C, Rule 3j
8	Thyroglobulin Antibody	50T, 2×50T,	690043，	6970341680320	Immunoassay for the in vitro quantitative determination of antibodies to	Annex VIII,

	(Electrochemiluminescence Immunoassay)	100T, 2×100T	690068，690036，690035	5016JA	thyroglobulin in human serum and plasma. Determination of anti-TG is used as an aid in the detection of autoimmune thyroid diseases. Intended testing population: Suspected autoimmune thyroid diseases people.	Class B, Rule 6
9	C-peptide (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	695022，695023，695011，695021	6970341680320 5043JD	Immunoassay for in vitro quantitative determination of C-peptide in human serum and plasma. Determination of C-peptide is used as an aid in the diagnosis and treatment of patients with abnormal insulin secretion. Intended testing population: Suspected abnormal insulin secretion people.	Annex VIII, Class B, Rule 6
10	Total Triiodothyronine Kit（Electrochemiluminescence Immunoassay）	50T, 2×50T, 100T, 2×100T	690048，690049，690050，690051	6970341680320 5011HY	Total Triiodothyronine Kit (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of total triiodothyronine (T3) in human serum and plasma by fully automated immunassay analyzer to aid evaluation of thyroid function. Intended testing population: Suspected thyroid diseases people.	Annex VIII, Class B, Rule 6
11	Total Thyroxine Kit（Electrochemiluminescence Immunoassay）	50T, 2×50T, 100T, 2×100T	690044，690045，690046，690047	6970341680320 5010HW	Total Thyroxine Kit (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of Total Thyroxine (T4) in human serum and plasma by fully automated immunassay analyzer to aid evaluation of thyroid function. Intended testing population:Suspected thyroid diseases people.	Annex VIII, Class B, Rule 6
12	Thyroxine-binding Globulin (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	690064，690065，690066，690067	6970341680320 5015J8	Thyroxine-binding Globulin (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of Thyroxine-binding Globulin (TBG) in human serum and plasma by fully automated immunassay analyzer to assisting diagnosis of thyroid diseases. Intended testing population: Suspected thyroid diseases people.	Annex VIII, Class B, Rule 6
13	Free Triiodothyronine Kit（Electrochemiluminescence Immunoassay）	50T, 2×50T, 100T, 2×100T	690056，690057，690058，690059	6970341680320 5013J4	Free Triiodothyronine Kit (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of free triiodothyronine (FT3) in human serum and plasma by fully automated immunassay analyzer to aid diagnosis of thyroid disorders and identify patients with T3 thyrotoxicosis. Intended testing population: Suspected thyroid diseases people.	Annex VIII, Class B, Rule 6
14	Free Thyroxine Kit (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	690052，690053，690054，690055	6970341680320 5012J2	Free Thyroxine Kit (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of free thyroxine (FT4) in human serum and plasma by fully automated immunassay analyzer to aid evaluation of thyroid function. Intended testing population:Suspected thyroid diseases people	Annex VIII, Class B, Rule 6
15	Thyroglobulin (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	690033，690034，690030，690029	6970341680320 5014J6	Thyroglobulin (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of thyroglobulin (Tg) in human serum and plasma by fully automated immunassay analyzer to aid in monitoring after thyroid ablation.	Annex VIII, Class B, Rule 6

					Intended testing population: Suspected thyroid-related diseases people.	
16	Estradiol (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	697031，697032，697033，697034	6970341680320 5058JS	Estradiol (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of 17β-estradiol (E2) in human serum and plasma, which is clinically used for auxiliary diagnosis of ovarian diseases. Intended testing population: Suspected ovarian diseases people.	Annex VIII, Class B, Rule 6
17	Follicle-stimulating Hormone (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	697019，697020，697025，697026	6970341680320 5055JL	Follicle-stimulating Hormone (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of follicle-stimulating hormone (FSH) in human serum and plasma by fully automated immunassay analyzer to evaluate pituitary endocrine function. Intended testing population: Suspected abnormal pituitary endocrine function people.	Annex VIII, Class B, Rule 6
18	Luteinizing Hormone (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	697015，697016，697017，697018	6970341680320 5056JN	Luteinizing Hormone (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of luteinizing hormone (LH) in human serum and plasma by fully automated immunassay analyzer to evaluate pituitary endocrine function. Intended testing population: Suspected abnormal pituitary endocrine function people.	Annex VIII, Class B, Rule 6
19	Prolactin (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	697027，697028，697029，697030	6970341680320 5057JQ	Prolactin (Electrochemiluminescence Immunoassay) is an immunoassay reagent for in vitro quantitative determination of Prolactin (PRL) in human serum and plasma by fully automated immunassay analyzer to evaluate the endocrine function of pituitary in clinic, and can not be used for the auxiliary diagnosis of hypophysoma.	Annex VIII, Class B, Rule 6
20	Testosterone (Electrochemiluminescence Immunoassay)	50T, 2×50T, 100T, 2×100T	697035，697036，697037，697038	6970341680320 5031J6	Immunoassay for in vitro quantitative determination of testosterone in human serum and plasma. Clinically used for the auxiliary diagnosis of diseases with abnormal level of testosterone. Intended testing population: People with suspected abnormal testosterone levels.	Annex VIII, Class B, Rule 6

Appendix II

No.	Product Name	Specification	REF No.	Basic UDI DI	Intended Purpose	Classification
1	HbA1c Calibrator	Level 1: 1×0.1mL, Level 2: 1×0.1mL	0320200201	69703416803 20200102JF	The HbA1c test system is intended for in vitro quantitative determination of glycated hemoglobin(HbA1c) content in human whole blood by the fully automated HPLC analyzer to aid diagnosis of diabetes mellitus. The HbA1c Calibrator is intended for calibration of glycated hemoglobin (HbA1c) assay on the hemoglobin analyzer.	Annex VIII, Class C, Rule 1.5, Rule 3k
2	HbA1c Control Material	Level 1: 1×0.1mL, Level 2: 1×0.1mL; Level 1: 1×0.5mL, Level 2: 1×0.5mL	0320200301; 0320200302	69703416803 20200101JD	The HbA1c test system is intended for in vitro quantitative determination of glycated hemoglobin(HbA1c) content in human whole blood by the fully automated HPLC analyzer to aid diagnosis of diabetes mellitus. The HbA1c Control Material is intended for quality control of glycated hemoglobin (HbA1c) assay on the hemoglobin analyzer.	Annex VIII, Class C, Rule 1.6 and Rule 3k
3	Chromatographic Column(HPLC)	GH-900Plus, H8, H9, H100, H100Plus	0320205, 0320207, 0320206, 0320214, 0320215	69703416801 20201GQ	The Chromatographic Column(HPLC) is intended for in vitro quantitative determination of glycated hemoglobin (HbA1c) content in human whole blood on the fully automated HPLC analyzer to aid diagnosis of diabetes mellitus.	Annex VIII, Class C, Rule 3
4	ß-THALASSAEMIA & HbA1c Calibrator	Level 1: 1×0.1mL Level 2: 1×0.1mL	0320200601	69703416803 20200202JL	The ß-THALASSAEMIA & HbA1c test system is intended for in vitro quantitative determination of HbA2、HbF and HbA1c content in human whole blood by the fully automated hemoglobin analyzer to diagnosis of ß-THALASSAEMIA and diabetes mellitus. The ß-THALASSAEMIA & HbA1c Calibrator is intended for calibration of HbA2/HbF/HbA1c assay on the hemoglobin analyzer.	Annex VIII, Class C, Rule 1.5, Rule 3k
5	ß-THALASSAEMIA & HbA1c Control Material	Level 1: 1×0.1mL Level 2: 1×0.1mL; Level 1: 1×0.5mL Level 2: 1×0.5mL	0320200701; 0320200702	69703416803 20200201JJ	The ß-THALASSAEMIA & HbA1c test system is intended for in vitro quantitative determination of HbA2, HbF and HbA1c content in human whole blood by the fully automated hemoglobin analyzer to diagnosis of ß-THALASSAEMIA and diabetes mellitus. The ß-THALASSAEMIA & HbA1c Control Material is intended for quality control of HbA2/HbF/HbA1c assay on the hemoglobin analyzer.	Annex VIII, Class C, Rule 1.6, Rule 3k

Appendix III

No.	Product Name	Specification	REF No.	Basic UDI DI	Intended Purpose	Classification
1	D-dimer Assay Kits (Lateral Flow Immunoassay)	10 Tests/kit, 25 Tests/kit, 50 Tests/kit, 100 Tests/kit	0320303501, 0320303502, 0320303503, 0320303504	69703416803203001HF	D-dimer assay kits (Lateral Flow Immunoassay) is an immunoassay reagent for in vitro quantitative determination of D-dimer in human plasma and whole blood by Lateral Flow Immunoassay Analyzer to excludes deep vein thrombosis (DVT) and pulmonary embolism (PE).	Annex VIII, Class C, Rule 3k